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PATENT COOPERATION TREATY

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NOTIFICATION OF RECEIPT OF PAPERS PURPORTING TO BE AN INTERNATIONAL APPLICATION

(PCT Administrative Instructions, Section 301)

Applicant's or agent's file reference: 7100527.WO1	Date of mailing (day/month/year): 16 OCT 2003
International application No.: PCT/IT 03/00617	IMPORTANT NOTIFICATION
Applicant: OLIVA Roberto (for all designated States)	Date of receipt (day/month/year): 13 OCT 2003

Title of the invention: An inhalator for single-dose mixtures in capsules.

1. The applicant is hereby notified that this receiving Office has received papers purporting to be an international application on the date of receipt indicated above.

2. The applicant's attention is drawn to the fact that these papers have not yet been checked by this receiving Office in respect of their compliance with the requirements of Article 11(1), that is, whether these papers meet the requirements necessary for the according of an international filing date.

3. As soon as this receiving Office has checked these papers, it will inform the applicant accordingly.

4. These papers have provisionally been given the international application number indicated above. The applicant is hereby requested to make reference to that number in all correspondence with this receiving Office.

Name and mailing address of the receiving Office: UFFICIO ITALIANO BREVETTI E MARCHI	Authorized officer: Sig. Giancarlo DE GIRONIMO
Facsimile No.	Telephone No.

Form PCT/RO/125 (July 1992)

PATENT COOPERATION TREATY

PCT

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

(PCT Article 36 and Rule 70)

Applicant's or agent's file reference 71O0527.WO1	**FOR FURTHER ACTION**	See Notification of Transmittal of International Preliminary Examination Report (Form PCT/IPEA/416)
International application No. PCT/IT 03/00617	International filing date *(day/month/year)* 13.10.2003	Priority date *(day/month/year)* 16.10.2002
International Patent Classification (IPC) or both national classification and IPC A61M15/00		
Applicant OLIVA, Roberto		

1. This international preliminary examination report has been prepared by this International Preliminary Examining Authority and is transmitted to the applicant according to Article 36.

2. This REPORT consists of a total of 6 sheets, including this cover sheet.

   ☒ This report is also accompanied by ANNEXES, i.e. sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications made before this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions under the PCT).

   These annexes consist of a total of 6 sheets.

3. This report contains indications relating to the following items:

   - I ☒ Basis of the opinion
   - II ☐ Priority
   - III ☐ Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
   - IV ☐ Lack of unity of invention
   - V ☒ Reasoned statement under Rule 66.2(a)(ii) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
   - VI ☐ Certain documents cited
   - VII ☐ Certain defects in the international application
   - VIII ☐ Certain observations on the international application

Date of submission of the demand	Date of completion of this report
13.05.2004	19.01.2005
Name and mailing address of the international preliminary examining authority: European Patent Office - P.B. 5818 Patentlaan 2 NL-2280 HV Rijswijk - Pays Bas Tel. +31 70 340 - 2040 Tx: 31 651 epo nl Fax: +31 70 340 - 3016	Authorized Officer Zeinstra, H Telephone No. +31 70 340-2824

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No. PCT/IT 03/00617

I. Basis of the report

1. With regard to the **elements** of the international application *(Replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report since they do not contain amendments (Rules 70.16 and 70.17))*:

Description, Pages

3-7	as originally filed
1, 1bis, 2, 2bis	received on 15.11.2004 with letter of 15.11.2004

Claims, Numbers

3-7	as originally filed
1-2	received on 15.11.2004 with letter of 15.11.2004

Drawings, Sheets

1/3-3/3	as originally filed

2. With regard to the **language**, all the elements marked above were available or furnished to this Authority in the language in which the international application was filed, unless otherwise indicated under this item.

   These elements were available or furnished to this Authority in the following language: , which is:

   - ☐ the language of a translation furnished for the purposes of the international search (under Rule 23.1(b)).
   - ☐ the language of publication of the international application (under Rule 48.3(b)).
   - ☐ the language of a translation furnished for the purposes of international preliminary examination (under Rule 55.2 and/or 55.3).

3. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application, the international preliminary examination was carried out on the basis of the sequence listing:

   - ☐ contained in the international application in written form.
   - ☐ filed together with the international application in computer readable form.
   - ☐ furnished subsequently to this Authority in written form.
   - ☐ furnished subsequently to this Authority in computer readable form.
   - ☐ The statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.
   - ☐ The statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished.

4. The amendments have resulted in the cancellation of:

   - ☐ the description, pages:
   - ☐ the claims, Nos.:
   - ☐ the drawings, sheets:

5. ☒ This report has been established as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed (Rule 70.2(c)).

   (Any replacement sheet containing such amendments must be referred to under item 1 and annexed to this report.)

   see separate sheet

6. Additional observations, if necessary:

   see separate sheet

V. Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Yes:	Claims	1-7
	No:	Claims	
Inventive step (IS)	Yes:	Claims	1-7
	No:	Claims	
Industrial applicability (IA)	Yes:	Claims	1-7
	No:	Claims	

2. Citations and explanations

   see separate sheet

Re Item I

1 The amendments filed with the letter dated 25.11.2004 introduce subject-matter which extends beyond the content of the application as filed, contrary to Article 34(2)(b) PCT. The amendments concerned are the following:

1.1 In the original set of claims, claim 3 is dependent on claim 2. With the letter dated 25.11.2004, the applicant has modified the original claim 1
- by incorporating partially the subject matter of original claim 3 without the feature "and having a sawtooth profile",
- by incorporating the feature "a cut portion of said capsule remaining external of the inhalator" taken from the description at page 4, lines 13 to 19, and
- **without** incorporating the subject matter of **original claim 2.**

1.2 **For the rest of the examination report, it has been considered that:**
- claim 1 of 25.11.2004 includes the subject matter of claim 2,
- the numbering of the dependent claims has not been changed, and thus claim 2 contains no features, and
- claim 3 contains only the feature "wherein said cutting edge has a sawtooth profile".

Re Item V

Reasoned statement under Rule 66.2(a)(ii) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

2 Reference is made to the following documents:
D1: EP-A-1 238 680 (PERA IVO) 11 September 2002 (2002-09-11)

3 The features of **claim 1 according to paragraph 1.2** is neither known from, nor rendered obvious by, the available prior art. Therefore the subject matter of claim 1 meets the requirements of Article 33(2) & (3) PCT. The reasons are as follows:

3.1 The document D1 is regarded as being the closest prior art to the subject-matter of

claim 1, and discloses (cf. page 13, line 32 - line 47, page 13, line 56 - page 14, line 31; figures 12, 13, 18-22) (the references in parentheses applying to this document):
An inhalator for single-dose mixtures in capsules comprising a main body (1) having an inhalation conduit (12), wherein:
the main body (1) comprises a first surface which extends planar and parallel to a longitudinal axis of the inhalation conduit (12) and exhibits a hole (4H) for communication with the inhalation conduit (12);
the inhalator also comprises a second body (3) which exhibits a second surface, shaped complementarily to the first surface and placed in contact with the first surface, on which first surface a housing (4H) is fashioned, into which housing (4H) a capsule (4) can be at least partially inserted; the second body (3) being rotatably coupled with the main body (1), and being able to rotate from an open position, in which the housing (4H) is accessible from outside for insertion of a capsule (4), and a closed position, in which the housing (4H) is aligned with the hole (4H);
the inhalator also comprises means for cutting (6H, 8H) for cutting off a portion of a capsule (4) which projects from the housing (4H) during rotation of the second body (3) from the open position to the closed position.

3.2 The subject-matter of claim 1 therefore differs from this known inhalator in that:
the first surface exhibits an overall shape which is a segment of a circle, with an apex thereof located in an intermediate position with respect to a longitudinal development of the inhalation conduit and comprises a pivot which is perpendicular to the first surface and arranged at the apex of the first surface, and a guide spur which is perpendicular to the first surface and arranged along an arced edge of the first surface, the guide spur having an undercut and a strike surface, said means for cutting comprising a cutting edge arranged peripherally on the first surface, a cut portion of said capsule remaining external of the inhalator.

3.3 This difference is neither known from nor rendered obvious by the available prior art. Therefore the subject matter of claim 1 meets the requirements of Article 33 (2) PCT.

3.4 This difference serves to prevent that the cut portion of the capsule falls into the reservoir together with the powder. A part of the powder may remain entrapped in this cut portion of the capsule, or the cut portion may lay into the reservoir obstructing the flow of the powder through the inhaler, in both cases causing an incomplete

inhalation of the powder. No hint of this feature for the same purpose can be found in the available prior art. Therefore the subject matter of claim 1 meet the requirements of Article 33 (3) PCT.

4 The inhalator of claim 1 is industrially applicable, and therefore the requirements of Article 33 (4) PCT are met.

5 Dependent claims 3 to 7 are preferred embodiments of claim 1. In view of that, claims 3 to 7 meet the requirements of Article 33(2) to (4) PCT.

Description

SINGLE DOSE INHALER

Technical Field

The invention relates to an inhalator for single-dose mixtures in capsules.

In particular, the inhalator enables inhalation of a mixture, typically powder, closed internally of a capsule made of plastic material which is wholly inserted into the inhalator.

Background Art

Inhalators of this type are known in the prior art and are constituted by a container comprising an inhalation conduit in communication with a chamber for housing a capsule containing a pharmaceutical substance to be inhaled. The housing chamber is elongate, and of a same shape as usual capsules for powder-form drugs, and is transversally arranged with respect to a longitudinal development of the inhalation conduit. Means for breaking open the capsule are associated to the housing chamber and arranged at ends thereof; the means for breaking are constituted by two piercing devices, including a number of sharp teeth which penetrate the housing chamber. The teeth are kept in an external position in relation to the chamber by a plurality of springs and exhibit a portion which is external to the container in which it is possible to exert a pressure with the fingers to cause perforation of the capsule. The powder can at this point exit from the capsule and be inhaled.

The known-type inhalators exhibit numerous drawbacks.

A main drawback is the presence of a relatively high number of components, considering the presence of the piercing devices, the springs and the manoeuvring

ends of the piercing devices. Some of these components are in relative motion with respect to the container and there is therefore a liability of malfunctioning or jamming. These components also require careful assembly operations in order to function correctly, which lead to an increase in cost of the inhalator.

Prior art inhalators also exhibit some functional defects. Firstly, perforation of the capsule does not guarantee complete exit of the medicinal substance, as the openings created are at ends of the capsule and small in size. To favour exit of the substance the inhalator has to be shaken and several inhalations performed, and still without the certainty of having consumed all of the capsule's contents. The position of the housing chamber, which is aligned with the inhalation conduit, is such that the passage of the medicinal substance from the chamber to the inhalation conduit is considerably obstructed. To favour inhalation the device has to be inclined in order to raise the inhalation chamber, and consequently the medicinal substance is not directly aspirated into the trachea but enters partly into contact with the inside of the mouth and is thus less effectively absorbed by the patient.

The main aim of the present invention is to obviate the above-described drawbacks by providing an inhalator for single-dose mixtures in capsules, which is characterised by having a limited number of components.

A further aim of the resent invention is to provide an inhalator in which the medicinal mixture is made available for inhalation by being completely transferred to the inhalation conduit.

A further aim of the present invention is to provide an inhalator in which the mixture is inhaled by means of a simple drawing-in of breath by the user.

Disclosure of Invention

Further characteristics and advantages of the present invention will better emerge from the detailed description that follows of an inhalator for single-dose mixtures

Claims.

1). An inhalator for single-dose mixtures in capsules comprising a main body (2) having an inhalation conduit (3), wherein:
the main body (2) comprises a first surface (10) which extends planar and parallel to a longitudinal axis of the inhalation conduit (3) and exhibits a hole (8) for communication with the inhalation conduit (3);
the inhalator also comprises a second body (4) which exhibits a second surface (14), shaped complementarily to the first surface (10) and placed in contact with the first surface (10), on which first surface (10) a housing (5) is fashioned, into which housing (5) a capsule (30) can be at least partially inserted; the second body (4) being rotatably coupled with the main body (2), and being able to rotate from an open position, in which the housing (5) is accessible from outside for insertion of a capsule (30), and a closed position, in which the housing (5) is aligned with the hole (8);
the inhalator also comprises means for cutting (11) for cutting off a portion of a capsule (30) which projects from the housing (5) during rotation of the second body (4) from the open position to the closed position.

2). The inhalator of claim 1, wherein:
the first surface (10) exhibits an overall shape which is a segment of a circle, with an apex thereof located in an intermediate position with respect to a longitudinal development of the inhalation conduit (3) and comprises a pivot (12) which is perpendicular to the first surface (10) and arranged at the apex of the first surface (10), and a guide spur (13) which is perpendicular to the first surface (10) and arranged along an arced edge of the first surface (10), the guide spur (13) having an undercut (13a) and a strike surface (13b).

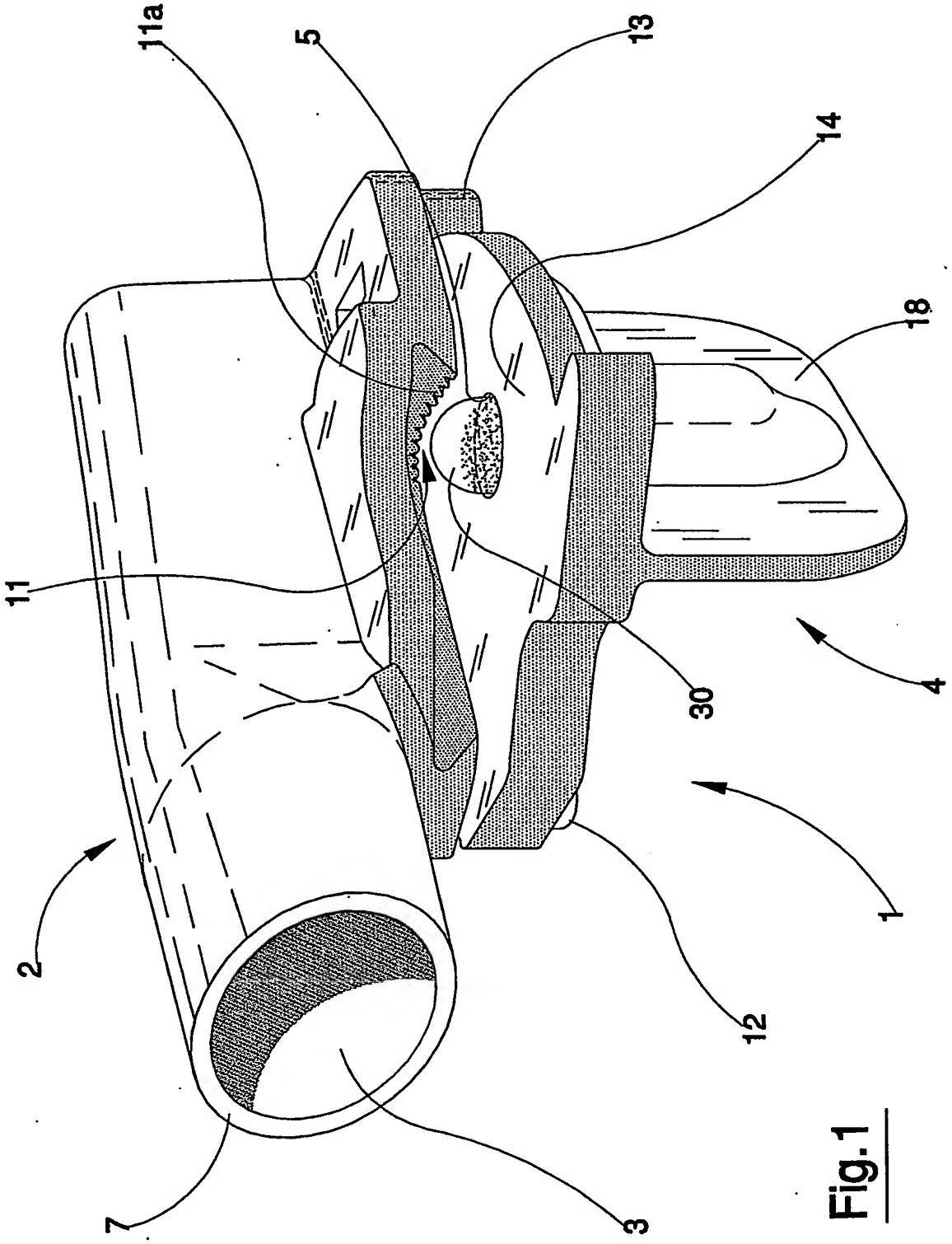
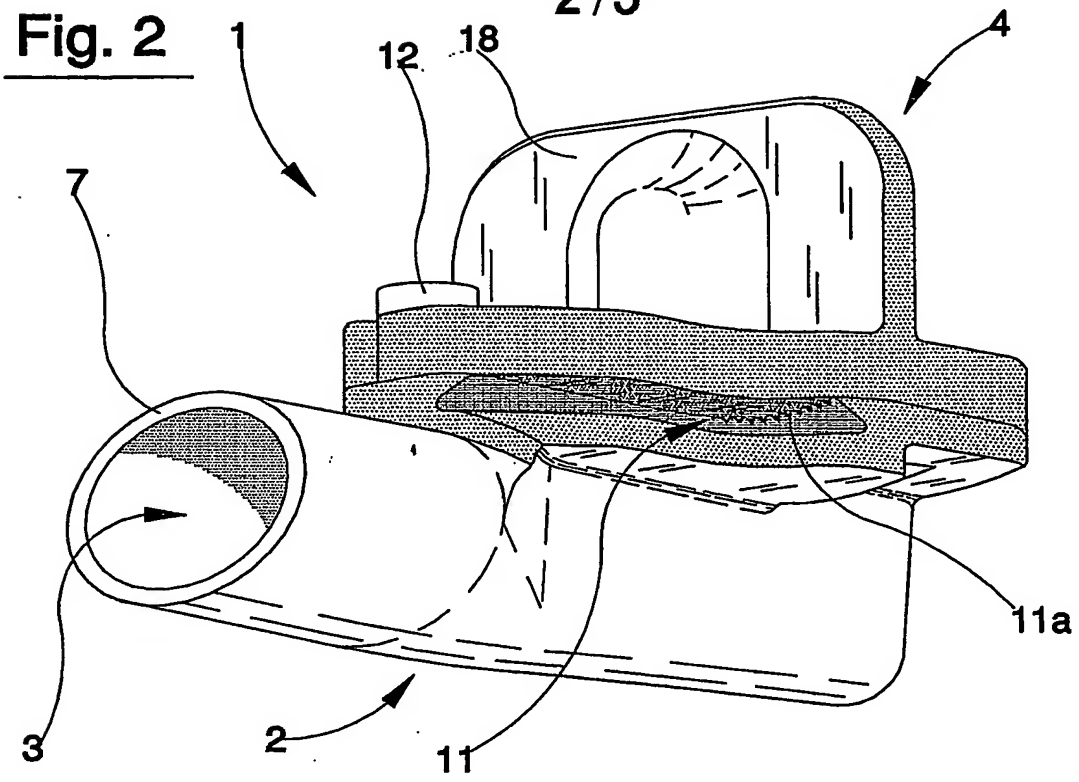


Fig.1

Fig. 2



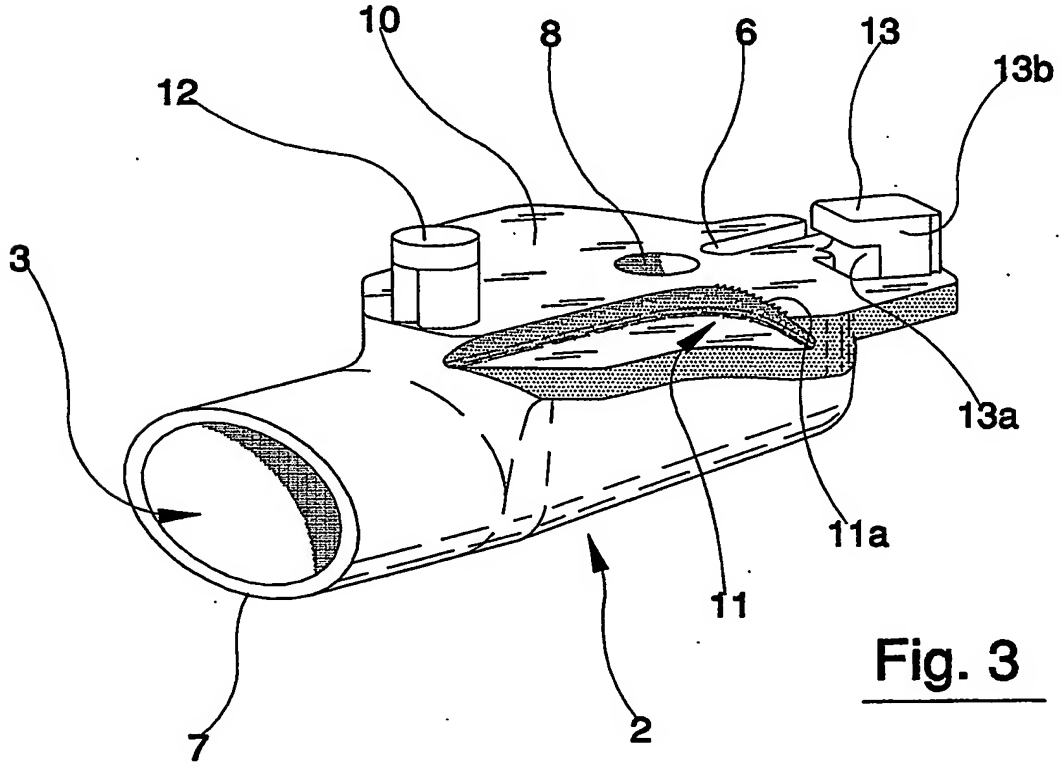


Fig. 3

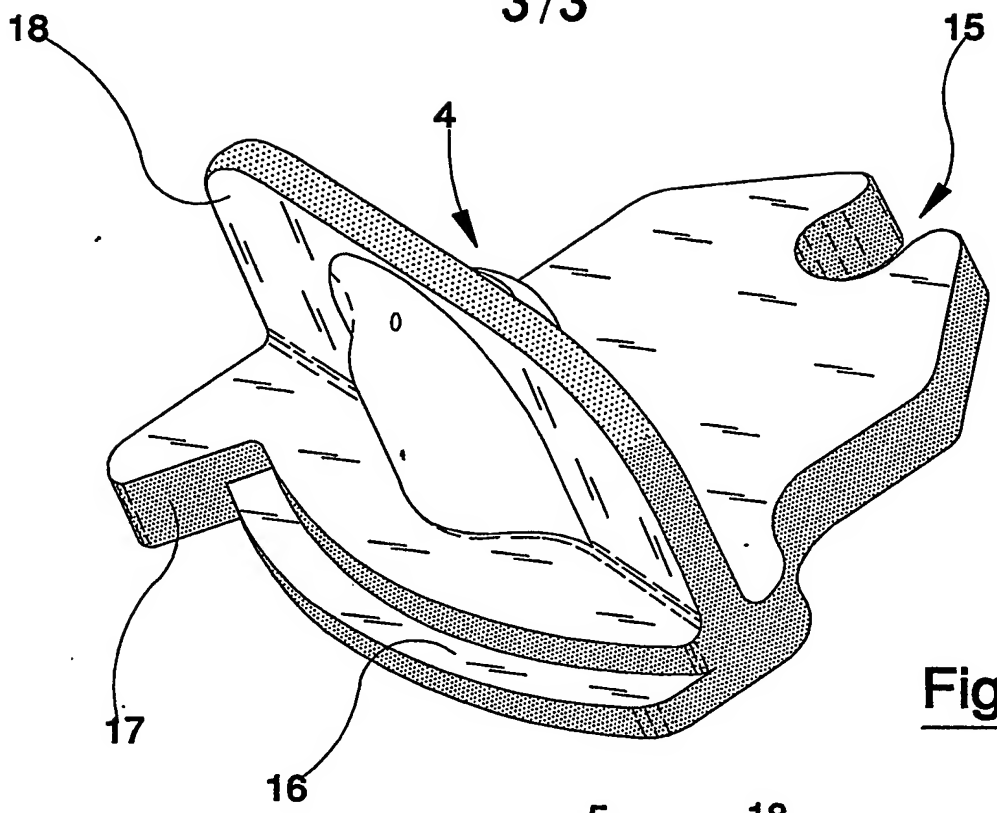
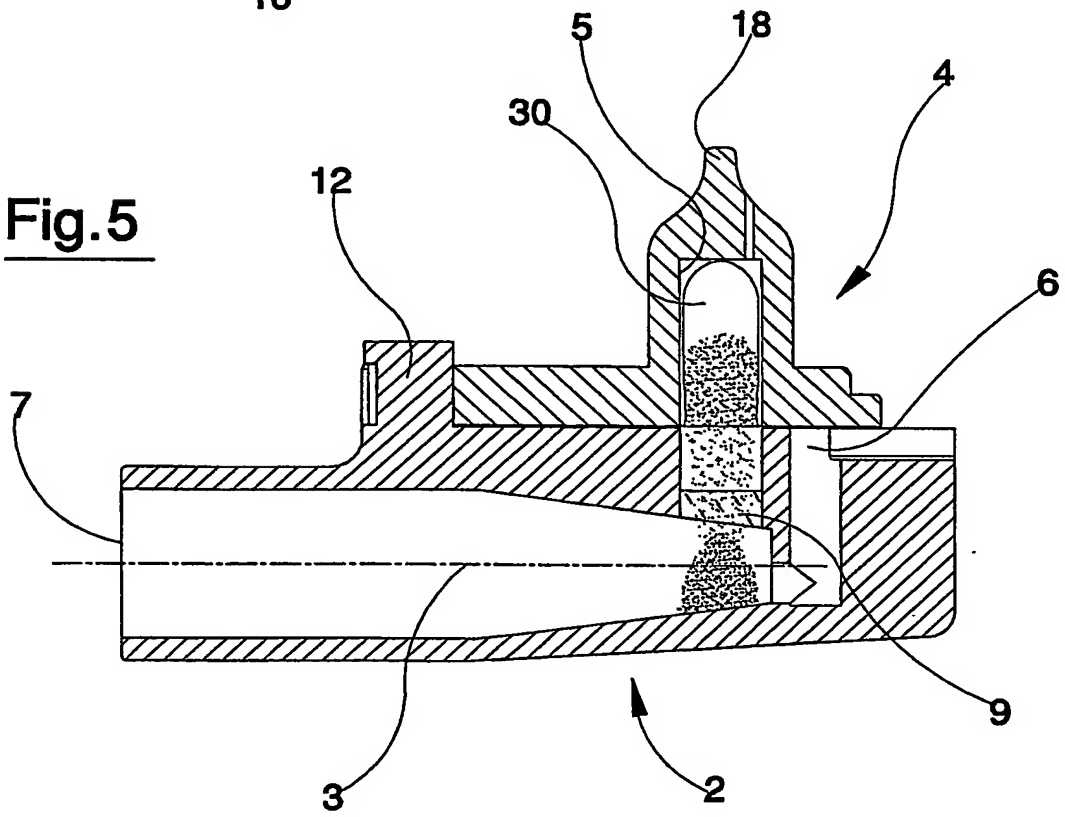


Fig.4

Fig.5



INTERNATIONAL SEARCH REPORT

Inter[illegible]ication No
PCT/IT 03/00617

A. CLASSIFICATION OF SUBJECT MATTER
IPC 7 A61M15/00

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
IPC 7 A61M

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)
EPO-Internal

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category °	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	EP 1 238 680 A (PERA IVO) 11 September 2002 (2002-09-11) page 13, line 32 - line 47; figures 12,13,18-22 page 13, line 56 -page 14, line 31	1,2
A	WO 97 27892 A (HOERLIN ERNST) 7 August 1997 (1997-08-07) page 4, line 2 -page 11, line 22; figures 1-8	1
A	DE 196 37 125 A (SCHUCKMANN ALFRED VON) 19 March 1998 (1998-03-19) column 4, line 2 -column 6, line 17; figures	1
A	WO 01 87393 A (INHALE THERAPEUTIC SYST) 22 November 2001 (2001-11-22)	

☐ Further documents are listed in the continuation of box C.

☒ Patent family members are listed in annex.

° Special categories of cited documents :

"A" document defining the general state of the art which is not considered to be of particular relevance

"E" earlier document but published on or after the international filing date

"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)

"O" document referring to an oral disclosure, use, exhibition or other means

"P" document published prior to the international filing date but later than the priority date claimed

"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.

"&" document member of the same patent family

Date of the actual completion of the international search	Date of mailing of the international search report
4 March 2004	11/03/2004

Name and mailing address of the ISA	Authorized officer
European Patent Office, P.B. 5818 Patentlaan 2 NL – 2280 HV Rijswijk Tel. (+31–70) 340–2040, Tx. 31 651 epo nl, Fax: (+31–70) 340–3016	Zeinstra, H

Form PCT/ISA/210 (second sheet) (July 1992)

INTERNATIONAL SEARCH REPORT

Information on patent family members

Inte[redacted] lication No
PCT/IT 03/00617

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